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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/673,739	10/20/2000	Thomas Valentine McCarthy	1377-156P	3757

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EXAMINER

TUNG, JOYCE

ART UNIT PAPER NUMBER

1637

DATE MAILED: 08/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

89-

Office Action Summary

Application No.

09/673,739

Applicant(s)

MCCARTHY ET AL.

Examiner

Joyce Tung

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 April 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 and 23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 and 23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The applicant's response filed April 30, 2004 to the Office action has been entered.

Claims 1-21 and 23 are pending.

I. Claims 1-5, 8, 10-12, 14-16, 20-21 and 23 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 4-7, 12-13, 15-19 of U.S. Patent No. 5,952,176 in view of Landegren (Technical focus, 1993, Vol. 9(6), pg. 199-204). Although the conflicting claims are not identical, they are not patentably distinct from each other because instant claims 1-5, 8, 10-12, 14-16, 20-21 and 23 of the instant application are drawn to a method of characterizing nucleic acid molecules comprising introducing a modified base which is a substrate of DNA glycosylase into a DNA molecule, excising the modified base by the DNA glycosylase, cleaving the DNA at the abasic site to generate an upstream DNA fragment that can be extended in the presence of an enzyme and a template nucleic acid and analyzing the resultant fragments. The claims 1, 2, 4-7, 12-13, 15-19 of U.S. Patent No. 5,952,176 are drawn to a method for rapidly detecting the presence or absence of a particular nucleic acid sequence at a candidate locus involving the steps in the instant claims 1-5, 8, 10-12, 14-16, 20-21 and 23.

However, the claims 1, 2, 4-7, 12-13, 15-19 of U.S. Patent No. 5,952,176 do not have the extension of the released upstream DNA fragment with a template nucleic acid and analyzing the resultant fragments.

It was well known in the art at the time of the instant invention that in vitro amplification reaction of DNA is proliferating DNA and it makes the method for the detection of DNA target molecule more sensitive (See the reference of Land-grant pg. 199). Therefore, it would have

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been prima facie obvious to further amplify DNA in the instant claims. Thus the instant claims are obvious over the claims 1, 2, 4-7, 12-13, 15-19 of U.S. Patent No. 5,952,176.

The response filed April 30, 2004 argues that the present invention allows to determine the nature of the 3' end of the extendible fragment and so generate diagnostic information regarding the 3' end of the extendible fragment, which directly relates to the DNA from which the extendible fragment was generated, while the method of Landegren (1993) uses the amplification to increase sensitivity. Although the purpose of both methods is different, the teachings of Landegren involve amplification method which reads on the limitation of step iv) of claim 1. As indicated in MPEP 2144, there is no requirement that the prior art provides the same reason as the applicant to make the claimed invention for establishing prima facie rejection.

Applicant's arguments filed April 30, 2004 have been fully considered but they are not persuasive, as indicated above. The rejection is maintained

2. Claims 1-21 and 23 remain rejected under 35 U.S.C. 102(b) as being anticipated by Dianov et al. (Molecular and Cellular Biology, 1992, Vol. 12(4), pg. 1605-1612).

Dianov et al. disclose that the extent and location of DNA repair synthesis in a double stranded oligonucleotide containing a single dUMP residue have been determined in which the repair pathway of a dUMP residue in DNA involves uracil- DNA glycosylase and incision of the phosphodiester bond 5' to AP site by an AP endonuclease and baseless sugar-phosphate residue could be excised by a dRpase or a 5'-3'exonuclease to leave a hydroxyl group at the 3' terminus (See pg. 1606, fig. 1) and then the polymerase step occur either after or before the excision step. The excision step is catalyzed usually by a DNA deoxyribophosphodiesterase (See pg. 1605, the Abstract).

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The response argues that Applicant not in the past and are not now, asserting the invention of cleavage at abasic sites to generate a 3' OH terminus. However, there is a limitation "cleaving the DNA at the abasic site so as to generate and release an extendible upstream DNA fragment having a 3' hydroxyl terminus (See claim 1, step iv).

The response next argues that the process of Dianov et al. requires the incorporation of 1-2 nucleotides by polymerase action of a down stream processing dRpase or exonuclease activity which is not required by the present invention. However, the claims are drawn to the method, which uses phrase "comprising". By using the phrase "comprising", there are many additional steps, which are applied to the method for performing the method.

The response further argues that Dianov et al. only disclose cleavage the 5' side, followed by action of 5' dRpase or 5' to 3' exonuclease, while the present method involves the cleavage on the 3' or the 5' side of the abasic site. Nevertheless, the limitations discussed herein are not in the claims.

Applicant's arguments filed April 30, 2004 have been fully considered but they are not persuasive as discussed above. The rejection is maintained.

Summary

3. No claims are allowable.

Conclusion

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

5. Any inquiries concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (571) 272-0790. The examiner can normally be reached on Monday-Friday from 8:00 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (571) 272-0782 on Monday-Friday from 10:00 AM-6:00 PM.

Any inquiries of a general nature or relating to the status of this application should be directed to the Chemical/Matrix receptionist whose telephone number is (703) 308-0196.

6. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Art Unit 1637 via the PTO Fax Center located in Crystal Mall 1 using (703) 305-3014 or 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Joyce Tung

August 18, 2004 *J.T.*

Kenneth R. Horlick
KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER

8/23/04